REMARKS

Claims 1 and 3-18 were pending. Claims 12, 14, and 16-18 have been canceled. Claim 1 has been amended. Claim 19 is new. Support for the claim amendments and the new claim can be found throughout the specification as filed. Therefore, no new matter has been added.

Importantly, the claim and specification amendments should not be construed to be an acquiescence to any of the claim rejections or objections to the specification. Rather, the amendments are being made solely to expedite the prosecution of the above-identified application. The Applicants expressly reserve the right to prosecute further the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

RESPONSE TO CLAIM REJECTIONS MADE UNDER 35 USC § 103(a)

Legal Standard

To establish a *prima facie* case of obviousness, a number of criteria must be met. For example, all of the limitations of a rejected claim must be taught or suggested in the references relied upon by the Examiner; or they must be among the variations that would have been "obvious to try" to one of ordinary skill in the relevant art in light of the cited references. Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the combination of cited references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Tamarkin 1, Davis and Sachetto

The Examiner contends that claims 1 and 3-18 are unpatentable over Tamarkin 1 (US 2006/0140984) in view of Davis (US 5,143,717), in further view of Sachetto (WO 96/03115). The Applicant respectfully traverses.

References do not teach or render the invention "obvious to try" in an enabled fashion

As noted by the Examiner, the combined teaching of Tamarkin 1 and Davis does not include all of the limitations of the rejected claims because, for example, none of the references discloses a hydrofluoroalkane propellant. However, the Examiner asserts that Sachetto does disclose a hydrofluoroalkane propellant.

An aerosol foam formulation containing a hydrofluoroalkane (HFA) propellant without a co-propellant was not "obvious to try" at the time of invention based on the cited references. As the Examiner mentions, Sachetto is the lone reference to disclose HFA propellants. However, the formulations described in Sachetto require the presence of a propellant or a co-propellant, in addition to the "foaming agent in the form of a water-immiscible liquefied gas," in order successfully to form a foam. Sachetto, page 10-11. Sachetto describes in detail the three kinds of aerosol containers that must be used with the described formulations: "the conventional 'monobloc' system; the 'bag-in-can' system and the 'can with piston' system." Sachetto, page 10, lines 30-31. Sachetto then discloses that the "bag-in-can" system and the "can with piston" system require a propellant separate from the formulation; that is, a propellant not in admixture with the formulation. The "monobloc" system similarly requires a co-propellant to be added to the can with the foamable composition. Nitrogen is the sole example provided by Sachetto of an appropriate additional propellant or co-propellant. In any kind of container, the formulations of Sachetto require the presence of an additional propellant or a co-propellant to form successfully a foam. Indeed, each example described in Sachetto is in the bag-in-can form and utilizes an additional propellant. Sachetto, page 12. Consequently, based on the cited references, one of ordinary skill would not have considered the use of a HFA propellant without a co-propellant "obvious to try."

Additionally, the claims have been amended to include additional limitations. The Applicant maintains that the combination of cited references fails to teach or render "obvious to try" the additional claim limitations in an enabled fashion. In other words, the cited references do not provide an enabling disclosure of the claimed invention. Given the description of the formulations in the cited references, one of ordinary skill in the art would not have been able to arrive at the claimed HFA-containing formulations without undue experimentation. Importantly,

the Federal Circuit recently held that a cited reference was unavailable as prior art under 35 USC § 102 and § 103 because it was not enabled. *Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc.*, 88 USPQ2d 1381 (Fed. Cir. 2008) ("*Impax v. Aventis*"). Thus, when "an ordinarily skilled artisan would have needed to experiment unduly to gain possession of the invention" the cited art does not qualify as prior art for that content, notwithstanding, e.g., a publication date prior to the priority date afforded the claims being examined or the validity of which is challenged. *See Impax v. Aventis*. Specifically, the reference in question contained only "broad and general" guidelines and lacked "sufficient direction or guidance" that specifically pointed to the claimed invention. *See Impax v. Aventis*. Importantly, the Applicant maintains that the challenges associated with preparing HFA-containing formulations are well-documented within this record and in the art, generally. None of the cited references provides any guidance whatsoever with respect to overcoming these challenges. Notwithstanding the fact that various topical formulations are known to contain many different components, and the fact that HFA propellants were known at the time of invention, in the parlance of *Impax* the Applicant maintains that the cited references do not provide sufficient direction or guidance to allow a skilled artisan to arrive at the claimed invention.

No reasonable expectation of success based on the cited references

Assuming *arguendo* that all of the limitations of a rejected claim are taught or suggested in an enabled fashion by the combination of references relied upon by the Examiner, or that any missing limitations are among the variations that would have been "obvious to try" to one of ordinary skill, the Applicant respectfully asserts that one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the claimed invention. A reasonable artisan would not have expected success in using hydrofluorocarbon propellants for immediate foaming emulsion compositions without the use of a separate propellant or without the use of lower volatile alcohols or both.

Importantly, Sachetto is the lone reference to disclose HFA propellants. However, as mentioned above, the formulations described in Sachetto require the presence of a propellant or a co-propellant, in addition to the "foaming agent in the form of a water-immiscible liquefied gas," in order successfully to form a foam. Sachetto, page 10-11. Therefore, Sachetto explicitly

teaches away from the claimed invention. Consequently, one of ordinary skill would not have had a reasonable expectation of success in developing the claimed invention based on the cited combination of references.

Along the same lines, "the omission of an element and retention of its function is an indicia of unobviousness." MPEP 2144.04, emphasis in original. Although the required co-propellant from the cited references is not reflected in the claims, the claimed formulations are efficacious foam-producing, HFA-containing aerosol formulations. Therefore, given the combined teachings of the cited references, one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the claimed invention (i.e., a foam-producing, HFA-containing aerosol formulation that does not comprise a co-propellant).

In further support of the contention that one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the present invention, the Applicant wishes to reiterate that Sachetto is the lone reference to mention HFA propellants. The examples provided in Sachetto only describe compositions comprising butane or "CFC's" as the foaming agent; no compositions comprising HFAs are exemplified. It is interesting to note that Sachetto uses a CFC propellant in an example (Sachetto, page 26), while earlier in the specification Sachetto describes that CFCs are undesirable propellants because of environmental reasons. We infer that Sachetto failed to overcome the well-documented challenges associated with developing HFA-based formulations, leading to the choice to exemplify the CFC-based formulation.

Furthermore, Sachetto provides no teaching as to why CFCs and HFAs would reasonably be considered interchangeable with alkane propellants (e.g., butane). Indeed, Sachetto describes only one example using a CFC propellant, and this example fails to make a successful foam as judged by Sachetto's own standards. Sachetto, page 26. The shortcomings of Sachetto's CFC-based formulation supports the Applicant's contentions that (i) these classes of propellants are not "drop-in" substitutes for each other, and (ii) significant reformulation must take place in order to arrive at a successful new formulation when the propellant is altered. Therefore, the disclosure of Sachetto would not have provided one of ordinary skill in the art with a reasonable expectation of success in reformulating any topical aerosol formulation with a different class of propellant.

With respect to the differences in solubility and compatibility between CFC and HFA propellants, the Examiner questions the persuasiveness of the teachings of Exhibits D and E because the teachings are not commensurate in scope with the claims. In response, claim 1 has been amended to require the presence of a non-ionic surfactant. The claimed formulations, therefore, contain HFA propellants and surfactants; whereas, the claimed formulations do not contain co-solvents or co-propellants, the very things which are suggested in the art to make HFAs workable as replacements for CFCs in formulations. The Applicants respectfully reiterate that, based on the state of the art, as summarized by Exhibits D and E, one of ordinary skill in the art would not have had a reasonable expectation of success in developing the claimed formulations based on the cited combination of references.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 USC § 103(a).

Tamarkin 2, Quigley and Sachetto

The Examiner further contends that claims 1 and 3-18 are unpatentable over Tamarkin 2 (US 2006/0233721) in view of Quigley, Jr. (US 6,075,056), in further view of Sachetto. The Applicant respectfully traverses.

References do not teach or render the invention "obvious to try" in an enabled fashion

As noted by the Examiner, the combined teaching of Tamarkin 2 and Quigley, Jr., does not include all of the limitations of the rejected claims because, for example, none of the references discloses a hydrofluoroalkane propellant. However, the Examiner asserts that Sachetto does disclose a hydrofluoroalkane propellant.

An aerosol foam formulation containing a hydrofluoroalkane (HFA) propellant without a co-propellant was not "obvious to try" at the time of invention based on the cited references. As the Examiner mentions, Sachetto is the lone reference to disclose HFA propellants. However, the formulations described in Sachetto require the presence of a propellant or a co-propellant, in addition to the "foaming agent in the form of a water-immiscible liquefied gas," in order successfully to form a foam. Sachetto, page 10-11. Sachetto describes in detail the three kinds of aerosol containers that must be used with the described formulations: "the conventional

'monobloc' system; the 'bag-in-can' system and the 'can with piston' system." Sachetto, page 10, lines 30-31. Sachetto then discloses that the "bag-in-can" system and the "can with piston" system require a propellant separate from the formulation; that is, a propellant not in admixture with the formulation. The "monobloc" system similarly requires a co-propellant to be added to the can with the foamable composition. Nitrogen is the sole example provided by Sachetto of an appropriate additional propellant or co-propellant. In any kind of container, the formulations of Sachetto require the presence of an additional propellant or a co-propellant to form successfully a foam. Indeed, each example described in Sachetto is in the bag-in-can form and utilizes an additional propellant. Sachetto, page 12. Consequently, based on the cited references, one of ordinary skill would not have considered the use of a HFA propellant without a co-propellant "obvious to try."

Additionally, the claims have been amended to include additional limitations. The Applicant maintains that the combination of cited references fails to teach or render "obvious to try" the additional claim limitations in an enabled fashion. In other words, the cited references do not provide an enabling disclosure of the claimed invention. Given the description of the formulations in the cited references, one of ordinary skill in the art would not have been able to arrive at the claimed HFA-containing formulations without undue experimentation. Importantly, the Federal Circuit recently held that a cited reference was unavailable as prior art under 35 USC § 102 and § 103 because it was not enabled. *Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc.*, 88 USPQ2d 1381 (Fed. Cir. 2008) ("*Impax v. Aventis*"). Thus, when "an ordinarily skilled artisan would have needed to experiment unduly to gain possession of the invention" the cited art does not qualify as prior art for that content, notwithstanding, e.g., a publication date prior to the priority date afforded the claims being examined or the validity of which is challenged. *See Impax v. Aventis*. Specifically, the reference in question contained only "broad and general" guidelines and lacked "sufficient direction or guidance" that specifically pointed to the claimed invention. *See Impax v. Aventis*. Importantly, the Applicant maintains that the challenges associated with preparing HFA-containing formulations are well-documented within this record and in the art, generally. None of the cited references provides any guidance whatsoever with respect to overcoming these challenges. Notwithstanding the fact

that various topical formulations are known to contain many different components, and the fact that HFA propellants were known at the time of invention, in the parlance of *Impax* the Applicant maintains that the cited references do not provide sufficient direction or guidance to allow a skilled artisan to arrive at the claimed invention.

No reasonable expectation of success based on the cited references

Assuming *arguendo* that all of the limitations of a rejected claim are taught or suggested in an enabled fashion by the combination of references relied upon by the Examiner, or that any missing limitations are among the variations that would have been "obvious to try" to one of ordinary skill, the Applicant respectfully asserts that one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the claimed invention. A reasonable artisan would not have expected success in using hydrofluorocarbon propellants for immediate foaming emulsion compositions without the use of a separate propellant or without the use of lower volatile alcohols or both.

Importantly, Sachetto is the lone reference to disclose HFA propellants. However, as mentioned above, the formulations described in Sachetto require the presence of a propellant or a co-propellant, in addition to the "foaming agent in the form of a water-immiscible liquefied gas," in order successfully to form a foam. Sachetto, page 10-11. Therefore, Sachetto explicitly teaches away from the claimed invention. Consequently, one of ordinary skill would not have had a reasonable expectation of success in developing the claimed invention based on the cited combination of references.

Along the same lines, "the omission of an element and retention of its function is an indicia of unobviousness." MPEP 2144.04, emphasis in original. Although the required co-propellant from the cited references is not reflected in the claims, the claimed formulations are efficacious foam-producing, HFA-containing aerosol formulations. Therefore, given the combined teachings of the cited references, one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the claimed invention (i.e., a foam-producing, HFA-containing aerosol formulation that does not comprise a co-propellant).

In further support of the contention that one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the present invention, the Applicant wishes to reiterate that Sachetto is the lone reference to mention HFA propellants. The examples provided in Sachetto only describe compositions comprising butane or "CFC's" as the foaming agent; no compositions comprising HFAs are exemplified. It is interesting to note that Sachetto uses a CFC propellant in an example (Sachetto, page 26), while earlier in the specification Sachetto describes that CFCs are undesirable propellants because of environmental reasons. We infer that Sachetto failed to overcome the well-documented challenges associated with developing HFA-based formulations, leading to the choice to exemplify the CFC-based formulation.

Furthermore, Sachetto provides no teaching as to why CFCs and HFAs would reasonably be considered interchangeable with alkane propellants (e.g., butane). Indeed, Sachetto describes only one example using a CFC propellant, and this example fails to make a successful foam as judged by Sachetto's own standards. Sachetto, page 26. The shortcomings of Sachetto's CFC-based formulation supports the Applicant's contentions that (i) these classes of propellants are not "drop-in" substitutes for each other, and (ii) significant reformulation must take place in order to arrive at a successful new formulation when the propellant is altered. Therefore, the disclosure of Sachetto would not have provided one of ordinary skill in the art with a reasonable expectation of success in reformulating any topical aerosol formulation with a different class of propellant.

With respect to the differences in solubility and compatibility between CFC and HFA propellants, the Examiner questions the persuasiveness of the teachings of Exhibits D and E because the teachings are not commensurate in scope with the claims. In response, claim 1 has been amended to require the presence of a non-ionic surfactant. The claimed formulations, therefore, contain HFA propellants and surfactants; whereas, the claimed formulations do not contain co-solvents or co-propellants, the very things which are suggested in the art to make HFAs workable as replacements for CFCs in formulations. The Applicants respectfully reiterate that, based on the state of the art, as summarized by Exhibits D and E, one of ordinary skill in the art would not have had a reasonable expectation of success in developing the claimed formulations based on the cited combination of references.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 USC § 103(a).

RESPONSE TO CLAIM REJECTIONS BASED ON NONSTATUTORY DOUBLE PATENTING

Claims 1, 12, and 13 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 48, and 49 of co-pending U.S. Patent Application No. 11/552,457. A Terminal Disclaimer over the cited application was submitted on October 10, 2008. Accordingly, withdrawal of the rejections under the judicially-created doctrine of obviousness-type double patenting is respectfully requested.

FEES

The Applicants believe that all of the fees required in connection with the filing of this paper have been provided. Nevertheless, the Director is hereby authorized to charge any additional required fee(s) to our Deposit Account, **06-1448**, reference **PDX-007.01**.

CONCLUSION

In view of the above remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,

FOLEY HOAG LLP

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